

REMARKS

Claims 2-9, 12, 13, 25 and 26 presently appear in this case. No claims have been allowed. The official action of July 29, 2003, has now been carefully studied.

Reconsideration and allowance are hereby respectfully urged.

Briefly, the present invention relates to a peptide corresponding to positions 89-96 of the human C-reactive protein (CRP) of the formula: Val₈₉-Thr-Val-Ala-Pro-Val-His-Ile₉₆ and modifications thereof obtained by substitution, elongation and amidation of the C-terminal or acylation of the N-terminal. The present peptides do not encompass the entire CRP. These peptides may be used to inhibit the enzymatic activity of human Leukocyte Elastase (hLE) and/or of human Leukocyte Cathepsin G (hCG) and can be used for the treatment of chronic inflammation conditions such as rheumatoid arthritis, pulmonary emphysema and cystic fibrosis.

Claims 2-9, 12, 13 and 25 have been rejected under 35 U.S.C. §112, first paragraph, written description. The examiner states that the recited proviso is not supported by the original disclosure. The examiner states that applicants' arguments are unconvincing because *In re Johnson* does not support any of the provisos that applicants propose. The examiner states that applicants do not have support in the original disclosure for the originally supported genus minus a

specific species. The examiner states that in *In re Johnson*, 194 USPQ 187 (CCPA 1977), Johnson was deleting two of the many choices which were disclosed, while in the present case, applicants are attempting to delete a choice which was not originally disclosed. This rejection is respectfully traversed.

The examiner's understanding of *In re Johnson* appears to be flawed. The present situation is almost exactly the same as that in *Johnson*. In *Johnson*, the claims are to a broad genus of polymer and many examples of species. For the purpose of this discussion, applicant will discuss claim A, as was discussed by the examiner. In claim A, applicant is claiming a genus. The present specification discloses many species. In *Johnson*, among the choices for the E and E' substituents were divalent sulphone and divalent carbonyl groups linking two aromatic nuclei. These two choices were excluded from the claim on appeal by means of a proviso. These choices are not individual species. Note footnote 12, at page 191, where *Johnson* states:

The provisos actually exclude more than species [1] and [2]. For example, polymers similar to species [1] and [2] but having substituted ring structures are also excluded.

See also page 196, where it states:

Appellants' grandparent application clearly describes the genus and the two special

classes of polymer materials excluded therefrom.

Thus, *Johnson* concluded that the written description was met.

Here, for claim A, the present specification clearly discloses the full genus, as well as the class of compounds in which the residue at 89 is Leu. The genus without the proviso clearly states in section (vii) that the Val at position 89 may be substituted by any hydrophobic amino acid residue, and claim 2 provides that the hydrophobic amino acid residue may be Leu. Thus, the class of peptides in which the residue at the 89 position is Leu is a disclosed class. As the genus is disclosed and the special class of peptide in which the residue at position 89 is Leu is disclosed, therefore the genus minus that special class of peptide is also disclosed sufficiently to comply with the written description requirement. This is the import of *In re Johnson*.

Accordingly, it is requested that the examiner reconsider his holding that there is something that distinguishes this case from that of *In re Johnson*. Once the examiner concedes that each of the claims of exhibits A-G would have been supported sufficiently to comply with the written description requirement of 35 U.S.C. §112 for the same reasons as enunciated in the *Johnson* case, then it is requested that the examiner again consider whether the cumulative effect of these claims as set forth in present

claim 5 is supported by the written description of 35 U.S.C. §112 for the same reasons and as previously argued. The examiner has not presented any separate reasons why this cumulative effect is not acceptable. Reconsideration and withdrawal of this rejection is therefore respectfully urged.

Claims 2, 3, 9 and 25 have been rejected under 35 U.S.C. §102(b) as being anticipated by Insley. The examiner states that Insley teaches a substantially pure protein comprising a mutant amino acid sequence of mammalian alpha-1 antitrypsin, wherein the methionine at amino acid position 358 is mutated to phenylalanine. This rejection is respectfully traversed.

In order to avoid this rejection, claim 25 has now been further amended to specify that the residue at 94 is not Phe when the other residues are as specified. With this amendment, Insley does not anticipate. Reconsideration and withdrawal of this rejection is therefore respectfully urged.

Claims 9, 12 and 13 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Insley. The examiner states that one of skill in the art would have been motivated to use the sequence taught by Insley for the treatment of conditions such as emphysema and other lung disorders related to progressive digestion of lung sacks, in

Appln. No. 09/10,380

Amdt. dated October 29, 2003

Reply to Office action of July 29, 2003

which the patient has an inadequate level of alpha-1 antitrypsin. This rejection is respectfully traversed.

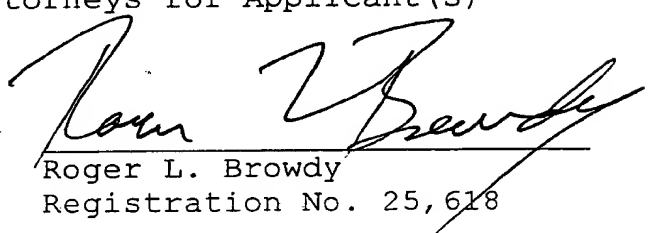
As discussed above, the present claims no longer read on the sequence of Insley. Thus, dependent claims 9, 12 and 13 are allowable for the same reasons as claim 25, from which they depend. Reconsideration and withdrawal of this rejection are therefore respectfully urged.

It is submitted that all of the claims now present in the case clearly define over the references of record and fully comply with 35 U.S.C. §112. Reconsideration and allowance are therefore earnestly solicited.

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.
Attorneys for Applicant(s)

By


Roger L. Browdy
Registration No. 25,618

RLB:gkw

Telephone No.: (202) 628-5197

Facsimile No.: (202) 737-3528

G:\BN\Y\YEDA\Fridkin1\pto\AmendmentJ.doc